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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/524,520	LOIBNER ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/14/08, 2/27/08 and 5/15/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-10,12-15,17-22,25-27,29-32,34-43 and 46-49* is/are pending in the application.

4a) Of the above claim(s) *1-5,7-10,12-15,17-22,25-27,29-32,34-43 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibits A and B*.

DETAILED ACTION

1. The amendment filed January 14, 2008, is acknowledged and has been entered. Claims 1, 3-4, 7-9, 13-15, 20-22, 29, 32, 34-36 and 40-43 have been amended. Claims 6, 11, 23-24, 28 and 33 have been canceled. Claims 46 and 47 have been newly added.

2. The supplemental amendment filed February 27, 2008, is acknowledged and has been entered. Claim 1 has been amended. Claims 16 and 44-45 have been canceled. Claim 48 has been newly added.

3. The supplemental amendment filed May 15, 2008, is acknowledged and has been entered. Claim 49 has been newly added.

4. Claims 1-5, 7-10, 12-15, 17-22, 25-27, 29-32, 34-43 and 46-49 are pending in the application.

5. Claims 1-5, 7-10, 12-15, 17-22, 25-27, 29-32, 34-43 and 46-48 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 24, 2007.

6. Claim 49 is under examination.

7. The following Office action contains NEW GROUNDS of rejection necessitated by amendment.

Election/Restriction

8. The amendment filed February 27, 2008, amends claims 1-5, 7-10, 12-15, 17-22, 25-27, 29-32, 34-43 and 46-47 and presents new claim 48, which are now directed to an invention that lacks unity with the originally elected invention for the following reasons:

In this case, the methods of claims 1-5, 7-10, 12-15, 17-22, 25-27, 29-32, 34-43 and 46-48, as amended, do not relate to the same single general inventive concept under PCT Rule 13.1 as the originally elected method of administering an antibody specific for Lewis Y during surgery, because, under PCT Rule 13.2, they lack the same or corresponding special technical feature.

In response to the requirement to elect a single invention, which is set forth in the Office action mailed April 11, 2007, Applicant has elected the invention of Group IV, claim 17, drawn to methods for the *intraoperative* treatment of tumors comprising administering an antibody specific for Lewis Y *during surgery*. Accordingly, for the reasons set forth in the restriction requirement, the special technical feature of the elected invention is the inhibition of dissemination of tumor cells by administering an antibody specific for Lewis Y *during* surgery.

However, the claims, as amended, now recite administering an antibody against a tumor-associated antigen, such as an antibody specific for EpCAM, NCAM, CEA, Lews Y, SialyI-TN, Globo H, GD2, GD3 or GM2 (see claim 17), 4 hours prior to surgery *and* during surgery (see claim 1). Accordingly, the claims, as would be amended are now drawn to inventions with multiple different special technical features, i.e., inhibiting the dissemination of tumor cells by administering an antibody specific for EpCAM, NCAM, CEA, Lews Y, SialyI-TN, Globo H, GD2, GD3 or GM2, within 4 hours prior to surgery *and* during surgery, respectively.

Therefore, it is apparent that the claims, as amended, are drawn to methods that have different special technical features than the special technical feature of the elected invention because the claims now recite administering the

antibody prior to surgery *and* during surgery, while the originally elected invention recited administering the antibody during surgery. Notably, as explained in the restriction requirement mailed 4/11/2007, the technical feature previously recited in claim 1 was the inhibition of dissemination of tumor cells by a process of administering an antibody directed against a tumor-associated antigen *during* surgery, which, as explained, lacks an inventive step over of Weitz et al (of record) in view of Nakashio et al. (of record). Therefore, it is apparent that the elected invention of administering an antibody during surgery does not share a special technical feature with a method of administering an antibody prior to surgery *and* during surgery, because the originally presented method of claim 1 does not define a contribution over the prior art. Furthermore, since the effectiveness of inhibiting tumor cell dissemination would depend on which antibody was being administered as well as when it was administered, methods of administering any particular antibody prior to surgery, during surgery or both prior to and during surgery would each require a different correlation to establish the effectiveness of each of these different methods, respectively. For these reasons, the claims, as amended, do not relate to the same single general inventive concept under PCT Rule 13.1 as the method originally presented. Finally, it is noted that PCT Rules 13.1 and 13.2 do not provide for a single general inventive concept to comprise more than the first mentioned product, the first mentioned method for making said product, and the first mentioned method for using said product. Accordingly, these newly presented methods for using the claimed antibodies do not form a single general inventive concept with the originally elected method.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-5, 7-10, 12-15, 17-22, 25-27, 29-32, 34-43 and 46-48 are withdrawn from consideration as being directed to nonelected inventions. See 37 CFR 1.142(b) and MPEP § 821.03. Applicant is further reminded that applicant cannot, as a matter of right, file a

request for continued examination (RCE) to obtain continued examination on the basis of claims which the examiner holds are drawn to an invention other than the one elected (see MPEP § 819 and 821.03).

Priority

9. With regards to the issue of priority, at page 10 of the response filed January 14, 2008, Applicant relies on foreign application Austria A-1217/2002, which is not in written in English, to attempt to establish a priority date of the present application of August 12, 2002.

In this case, while a certified copy of foreign application Austria A 1217/2002 has been placed of record in the file, Applicants have not provided a verified or certified translation of document Austria A-1217/2002. Therefore, the effective filing date of the instant claims is the filing date of PCT/AT03/00219, i.e., July 31, 2003. See 37 CFR 1.55. See MPEP § 201.15.

Notably, when Applicant relies upon a document in a language other than English 37 CFR § 41.154 states:

> When a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an affidavit attesting to the accuracy of the translation must be filed with the document.

In summary, because a translation of the document into English and an affidavit attesting to the accuracy of the translation has not been filed, the effective filing date of the claims is July 31, 2003.

Information Disclosure Statement

10. The references cited in the information disclosure statement filed on March 7, 2008, have been considered.

Grounds of Objection and Rejection Withdrawn

11. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed August 13, 2007, have been

obviated or rendered moot by Applicant's amendment and/or arguments filed January 14, 2008, February 27, 2008, or May 15, 2008.

Notably, the previous grounds of rejection under 35 U.S.C. 103(a) have been rendered moot because, e.g., claim 49 does not recite administering an antibody specific for the Lewis Y antigen.

New Grounds of Objection

Claim Objections

12. Claim 49 is objected to as being drawn in the alternative to the subject matter of non-elected inventions (i.e., methods of administering an antibody prior to surgery or methods of administering an antibody prior to surgery and during surgery).

Appropriate correction is required.

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. The rejection of claim 49 under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,716,595 (of record), is maintained.

Claim 49 is herein drawn to methods of administering to a patient during surgery a preparation consisting of an antibody directed against a tumor-associated antigen and at least one pharmaceutically acceptable carrier selected from the group consisting of an auxiliary substance, a buffer, a salt and a preservative whereby immunocomplexing of tumor cells within the scope of the surgical intervention inhibits dissemination of tumor cells, and wherein said immunocomplexing activates an antibody-dependent cellular cytotoxicity effector function and a complement dependent cytotoxicity effector function.

At page 9 of the amendment filed January 14, 2008, Applicant has traversed this ground of rejection.

In this traversal, Applicant appears to be arguing that US Patent No. 5,716,595 does not teach administering a composition consisting of a tumor-associated antibody and a least one auxiliary substance, buffer, salt or a preservative to a cancer patient *during* surgery.

In response, this argument is not found persuasive, because as explained in the previous Office action, US Patent No. 5,716,595 teaches methods for the intraoperative treatment of tumors comprising administering tumor-associated antibodies to patients *during surgical treatments* (see entire document, e.g., column 10, lines 31-61 and column 13, lines 8-18). Notably, according to Dorlands Medical Dictionary, the term "intraoperative" is defined as "occurring during a surgical operation" (*Copyright 2007. An Elsevier publication. All rights reserved.*) (see attached Exhibit A) and therefore, it is apparent that US Patent No. 5,716,595 teaches administering tumor-associated antibodies during surgery. Furthermore, at column 3, lines 25 to 31, US Patent No. 5,716,595 expressly teaches "a method for close-range tumor detection and treatment during an operative, intravascular or endoscopic procedure. The method comprises injecting a patient subject to such a procedure parenterally with an effective amount of a labeled protein which specifically binds a substance

produced by or associated with a targeted tumor"[1]. While this particular disclosure does not expressly identify labeled antibodies as such a labeled protein, other disclosures in US Patent No. 5,716,595 teach that labeled antibodies are species of labeled proteins (see e.g., column 9, lines 25-47). Finally, US Patent No. 5,716,595 teaches sterile injectable preparations for human use comprising labeled antibody which would inherently comprise at least one auxiliary substance, buffer, salt or a preservative.

Furthermore, while the instant claim recites antibody and not a labeled antibody, the instant specification at page 13 exemplifies the antibodies of the invention as including "antibodies of any type" (see second new paragraph" and teaches that "antibody fragments, conjugates, homologues or derivatives" may be used (see forth new paragraph). Accordingly, it is apparent that the compositions of labeled tumor-associated antibody conjugates of US Patent No. 5,716,595 which are administered to patients during surgery are structurally and materially indistinguishable from the instantly recited composition consisting of an "antibody of any type, such as an antibody conjugate", directed against a tumor-associated antigen and at least one auxiliary substance, buffer, salt or preservative administered during surgery. In this case, the specification does not exclude labeled antibodies, such as those taught by US Patent No. 5,716,595, from the genus of antibodies to be administered. For this reason, the compositions of labeled antibodies of US Patent No. 5,716,595 would be considered a species of the instantly claimed compositions of an "antibody" and at least one other auxiliary substance. Furthermore, while US Patent No. 5,716,595 does not expressly teach that the antibodies of the invention activate antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector functions, US Patent No. 5,716,595 teaches that the antibodies of the invention include whole antibodies of any class, e.g., IgG, IgM, IgE, IgA, or IgD (see e.g., column 12, lines 32-65) which comprise Fc domains that activate antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity

[1] Underlining added

effector functions. For these reasons, the processes of US Patent No. 5,716,595 remain manipulatively and materially indistinguishable from the claimed processes. Thus, absent a showing of any difference, the claimed processes are still deemed the same as that disclosed in the prior art.

For these reasons and as further explained in the previous Office action, and after careful and complete consideration, the Examiner disagrees with Applicant's contention that US Patent No. 5,716,595 no longer anticipates the instant claim and the rejection of claim 49 under 35 U.S.C. 102(b), as being anticipated by US Patent No. 5,716,595, is maintained.

15. The rejection of claim 49 under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,107,102 (of record), is maintained.

The instant claim is described in the above rejection of the claim as being anticipated by US Patent No. 5,716,595.

At page 10 of the amendment filed January 14, 2008, Applicant has traversed this ground of rejection.

In this traversal, Applicant appears to be arguing that the antibody conjugates of US Patent No. 6,107,102 cannot activate antibody-dependent cellular toxicity and complement dependent cytotoxicity functions.

In response, this argument is not found persuasive, because US Patent No. 6,107,102 teaches that the antibody conjugates of the invention can comprise whole antibodies such as an IgG antibody (see e.g., column 11, lines 24-33) which comprises an Fc domain that activates antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector functions. Accordingly, while US Patent No. 6,107,102 does not expressly teach that the antibody conjugates of the invention activate antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector functions, the antibody conjugates of US Patent No. 6,107,102 comprise an Fc domain that activates antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector function and Applicant has not submitted any evidence to

reasonably establish that the antibody conjugates of US Patent No. 6,107,102 do not activate antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector functions.

Notably, the Office does not have the facilities for examining and comparing the antibody conjugates of the prior art in order to establish that the antibody conjugates of the prior art do not possess the same material, structural, and functional characteristics as Applicant's "antibody". In the absence of evidence to the contrary, the burden is upon the applicant to prove that the antibody used in the method to which the claims are directed is different than that taught by the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA, 1977) and *Ex parte Gray*, 10 USPQ2d 1922 1923 (PTO Board of Patent Appeals and Interferences, 1988 and 1989).

In this case, the instant specification at page 13 exemplifies the antibodies used in the processes of the invention as including "antibodies of any type" (see second new paragraph" and teaches that "antibody fragments, conjugates, homologues or derivatives" may be used (see forth new paragraph). Accordingly, it is apparent that the compositions of tumor-associated antibody conjugates of US Patent No. 6,107,102 which are administered to patients during surgery are structurally and materially indistinguishable from the instantly recited composition consisting of an "antibody of any type" directed against a tumor-associated antigen and at least one auxiliary substance, buffer, salt or preservative administered during surgery. In this case, the specification does not exclude antibody conjugates, such as those taught by US Patent No. 6,107,102, from the genus of "antibodies" to be administered. For this reason, the compositions of antibody conjugates of US Patent No. 6,107,102 would be considered to be species of the instantly claimed compositions of an antibody and at least one other auxiliary substance. Accordingly, the processes of US Patent No. 6,107,102 remain manipulatively and materially indistinguishable from the claimed processes. Thus, absent a showing of any difference, the claimed processes are still deemed the same as that disclosed in the prior art.

For these reasons and as further explained in the previous Office action, and after careful and complete consideration, the Examiner disagrees with Applicant's contention that US Patent No. 6,107,102 no longer anticipates the instant claim and the rejection of claim 49 under 35 U.S.C. 102(b), as being anticipated by US Patent No. 6,107,102, is maintained.

16. The rejection of Claim 49 under 35 U.S.C. 102(e) as being anticipated by US Patent 6,949,342 (of record), is maintained.

The instant claim is described in the above rejection of the claim as being anticipated by US Patent No. 5,716,595.

At page 10 of the amendment filed January 14, 2008, Applicant has traversed this ground of rejection.

In this traversal, Applicant argues that the instant application has established a priority date of August 12, 2002, but that US Patent 6,949,342 only has a priority date of December 21, 2001.

In response, this argument is not found persuasive because Applicant is relying on foreign application, Austria A 1217/2002, which is not in written in English, to attempt to establish a priority date of the present application of August 12, 2002.

In this case, while a certified copy of foreign application Austria A 1217/2002 has been placed of record in the file, Applicant has not provided a verified or certified translation of document, Austria A 1217/2002. Therefore, as explained above, the effective filing date of the instant claims is the filing date of PCT/AT03/00219, i.e., July 31, 2003. See 37 CFR 1.55. See MPEP § 201.15. If Applicant wishes to establish a priority date of August 12, 2002, it is suggested that a translation of the document into English and an affidavit attesting to the accuracy of the translation be made of record.

Furthermore, as set forth in the previous Office action, US Patent 6,949,342 teaches methods of treating prostate tumors comprising administering antibodies to patients during surgery either intravenously (i.e. systematically)

and/or locally (see entire document, e.g., column 30, lines 1-49), wherein the antibodies are directed against a tumor-associated surface antigens or tumor-associated antigens, such as antibodies directed against Platelet Derived Growth Factor Receptor, a prostatic epithelial tumor cell associated surface antigen and/or antibodies directed against HoxC6, a prostatic epithelial tumor cell associated antigen (e.g., column 10, lines 36-67). Additionally, US Patent 6,949,342 teaches that the antibody compositions can further contain at least one salt such as a saline solution (see e.g., column 27).

Finally, while US Patent 6,949,342 does not expressly teach that the antibody conjugates of the invention activate antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector functions, US Patent 6,949,342 teaches that the antibodies of the invention include whole antibodies such as an IgG antibody (see e.g., column 20, lines 4-7) which comprises an Fc domain that activates antibody-dependent cellular cytotoxicity and complement dependent cytotoxicity effector functions. Accordingly, it is apparent that the compositions of tumor-associated antibodies of US Patent No. 6,949,342 administered to patients during surgery are structurally and materially indistinguishable from the instantly recited composition consisting of an antibody directed against a tumor-associated antigen and at least one auxiliary substance, buffer, salt or preservative administered during surgery. In this case, the processes of US Patent No. 6,949,342 remain manipulatively and materially indistinguishable from the claimed processes. Thus, absent a showing of any difference, the claimed processes are still deemed the same as that disclosed in the prior art.

For these reasons and as further explained in the previous Office action, and after careful and complete consideration, the Examiner disagrees with Applicant's contention that US Patent No. 6,949,342 no longer anticipates the instant claim and the rejection of claim 49 under 35 U.S.C. 102(e), as being anticipated by US Patent No. 6,949,342, is maintained.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. The provisional rejection of claim 49 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 21[2] of copending Application No. 10/558,166, is maintained for the reasons of record, as explained in the previous Office action.

At page 11 of the amendment filed January 14, 2008, Applicant submits that this rejection will be addressed upon the finding of patentable subject matter in the present application.

In response, the pending claims in these applications have not been amended sufficiently to overcome this provisional rejection and it will be maintained until it is appropriately resolved.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description'' Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereinafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled

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[2] Claim 21 in 10/558,166 now recites administering an antibody with surgery.

in the art would recognize that the applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention.*

In the instant case, the claim is drawn to a process of administering a preparation that comprises a structurally and/or functionally diverse genus of at

least one "auxiliary substance". Notably, while the specification discloses at page 14, last full paragraph, that the preparations of the invention preferably include "auxiliary substances", the specification otherwise does not provide any description of an "auxiliary substance", or any guidance as to what an "auxiliary substance" is or how an "auxiliary substance" is made. Notably, according to Dictionary.com, the term "auxiliary" can be defined as meaning "additional" (Copyright © 2008, Lexico Publishing Group, LLC. All rights reserved.) (see attached Exhibit B). Accordingly, because the specification does not provide any specific guidance or direction as to what structures these "additional substances might have, one of skill in the art would not be able to immediately envision, recognize or distinguish an "auxiliary substance" from any other subject matter; and therefore the specification would not reasonably convey that Applicant was in possession of preparations comprising "auxiliary substances" at the time the application was filed.

Applicant is reminded that "generalized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). In this instance, as in that, there is no language that adequately describes with clarity and particularity the genus of "auxiliary substances" that can be used in practicing the claimed process, so as to achieve the claimed therapeutic effect.

Notably the function or effect of the "auxiliary substance" is not specified, either in the claim or in the disclosure, such that it would be possible to immediately envision, recognize or distinguish those "auxiliary substances" that can be used in practicing the claimed process, so as to achieve the claimed therapeutic effect, from other substances.

Then, even if it were to be presumed that the "auxiliary substance" must have therapeutic effect (e.g., must inhibit the dissemination of tumor cells when administered intraoperatively in combination with the antibody), it is aptly noted that the Federal Circuit has decided that a generic statement that defines a genus of substances by *only* their functional activity, i.e., the ability to achieve

therapeutic effect by whatever mode of operation, does not provide an adequate written description of the genus. See *The Reagents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (CAFC 1997). The Court indicated that while applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a precise definition of a representative number of members of the genus, such as by reciting the structure, formula, chemical name, or physical properties of those members, rather than by merely reciting a wish for, or even a plan for obtaining a genus of molecules having a particular functional property. The recitation of a functional property alone, which must be shared by the members of the genus, is merely descriptive of what the members of genus must be capable of doing, not of the substance and structure of the members.

Although *Lilly* related to claims drawn to genetic material, the statute applies to all types of inventions. "Regardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to the subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods". *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1894 (CAFC 2004). The claimed method depends upon finding an "auxiliary substance" that can be used in practicing the claimed process, so as to achieve the claimed therapeutic effect; without such a compound, it is impossible to practice the invention.

In addition, although the skilled artisan could potentially identify "auxiliary substances" that might be used in practicing the claimed invention by screening for substances that are capable of inhibiting the dissemination of tumor cells when administered intraoperatively in combination with the antibody, it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Conclusion

21. No claims are allowed.

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,624,659 (of record) teaches locally administering an antibody directed against the tumor-associated antigen, tenascin, into surgical resection cavities of glioblastoma patients during surgery.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
July 31, 2008